#### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS SHERMAN DIVISION

ADVANCED NEUROMODULATION \$

SYSTEMS, INC. \$

V. \$ No. 4:04cv131

SADVANCED BIONICS CORPORATION \$

# MEMORANDUM OPINION AND ORDER CONSTRUING CERTAIN CLAIMS OF UNITED STATES PATENT NOS. 4,793,353, 6,216,045 AND 6,154,678

On April 15, 2005, counsel for the parties appeared before the Court for the purpose of presenting evidence and argument that would assist the Court in interpreting the meaning of certain disputed terms in the claims of United States Patent Nos. 4,793,353 ("the '353 patent"), 6,216,045 ("the '045 patent"), and 6,154,678 ("the '678 patent"). Having considered the parties' proposed claim constructions, briefs, the testimony and exhibits admitted into evidence, the patents and the argument of counsel, the Court now makes the following findings and construes the disputed terms as follows.

#### STANDARD FOR CONSTRUING CLAIM TERMS

In Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) ("Markman I"), the Federal Circuit held that claim construction is a matter of law. In affirming this decision, the Supreme Court in Markman v. Westview Instruments, Inc., 116 S.Ct. 1384 (1996) ("Markman II"), stated, "[W]e hold that the

construction of a patent, including terms of art within its claims, is exclusively within the province of the court," *Id.* at 1387, and "...judges, not juries, are the better suited to find the acquired meaning of patent terms." *Id.* at 1395.

The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly. In the exercise of that duty, the trial judge has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties. (citations omitted)

Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1555 (Fed.Cir. 1995).

Since the *Markman* decision, the Federal Circuit Court of Apeals has issued many opinions which provide guidance to a trial court in performing this duty.

The Court should first look to the intrinsic evidence of record, that is, the patent itself, including the claims, the specification, and, if in evidence, the prosecution history. See Markman I, 52 F.3d at 979; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996). Although intrinsic evidence is the most significant source of the meaning of disputed claim language, all intrinsic evidence is not equal. See Vitronics at 1582. "The first requirement in claim interpretation is to examine the claim language." SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 882 (Fed. Cir. 1988). There is a "heavy presumption in favor of the ordinary meaning of claim

language." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). "Claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources." Id. at 989-990. Such invitation occurs when the patentee has set forth an explicit definition for a claim term, or when there is no means by which the scope of the claim can be ascertained from the language used. Id.; see also York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 U.S.P.Q. 2d 1619, 1622 (Fed. Cir. 1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.").

This is not to say that claim terms are to be construed in a vacuum. A word in a patent claim must be interpreted as one of ordinary skill in the art would interpret it unless it is apparent from the patent and prosecution history the inventor used the term with a different meaning. Usually, the specification is the "single best guide" to the meaning of a disputed term and may serve as a dictionary, defining the particular meaning of terms used in the claims. Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 979.

Claims must be read in view of the specification, of which they are a part. Autogiro, 384 F.2d at 397, 155 USPQ at 702; see Winans v. Denmead, 56 U.S. (15 How.) at 338; Bates v. Coe, 98 U.S. at 38-39. The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention.

For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims.

Markman I, 52 F.3d at 979.

The Federal Circuit offered guidance on how the written description can be helpful in determining the meaning of claims in *SciMed Life Sys. v. Advanced Cardiovascular* Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001).

While it is true, of course, that "the claims define the scope of the right to exclude" and that "the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim," Renishaw PLC, 158 F.3d at 1248, 48 USPQ 2d at 1121, the written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.

Id.

The Court must always bear in mind, however, that the claim and not the specification measures the invention. *Envtl. Designs*, *Ltd. v. Union Oil. Co. of Cal.*, 713 F.2d 693, 699 (1983).

If, after reviewing all available intrinsic evidence, some genuine ambiguity still exists in the claims, the Court may use extrinsic evidence as an aid in construing the claim language.

Vitronics 90 F.3d at 1584. Extrinsic evidence may be considered if needed to assist in determining the meaning or scope of technical terms in the specification or claims to one of ordinary skill in the art. Vitronics 90 F.3d at 1583. The Court may always consider extrinsic evidence from expert witnesses "for

background and education on the technology" at issue. Key Pharm. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).

Further, a trial court may rely on expert testimony in construing a claim when the intrinsic evidence does not answer a particular question. *Vitronics* 90 F.3d at 1584. A court may only rely on such extrinsic evidence so long as it does not vary on the claim construction mandated by the claims and the patent itself. *Key Pharm.*, 161 F.3d at 716.

A dictionary is not prohibited extrinsic evidence, and is an available resource of claim construction. Although a dictionary definition may not enlarge the scope of a term when the specification and the prosecution history show that the inventor, or recognized usage in the field of the invention, have given the term a limited or specialized meaning, a dictionary is often useful to aid the court in determining the correct meaning to be ascribed to a term as it was used.

Vanguard Pro. Corp. v. Parker Hannifin Corp., 234 F.3d. 1370 1372 (Fed. Cir. 2000).

As a general rule, patent claims should be interpreted to sustain their validity, if possible.

In Phillips v. AWH Corp., No. 03-1269-1286, 2005 LEXIS 13954, 75 U.S.P.Q. 2d 1321 (Fed. Cir. July 12, 2005), the United States Court of Appeals, Federal Circuit, sitting en banc, substantially reaffirmed all of the foregoing principles, but clarified some of them. As the court stated,

[W]hat we stated in those cases bears restating, for the basic principles of claim construction outlined there are still applicable, and we reaffirm them today. We have also previously considered the use of dictionaries in claim construction. What we have said in that regard requires clarification.

Id. at \*20.

In making this clarification, the Court stated:

Although the principles outlined above have been articulated on numerous occasions, some of this court's cases have suggested a somewhat different approach to claim construction, in which the court has given greater emphasis to dictionary definitions of claim terms and has assigned a less prominent role to the specification and the prosecution history. The leading case in this line is *Texas Digital Systems*, *Inc. v. Telegenix*, *Inc.*, 308 F.3d 1193 (Fed. Cir. 2002).

In *Phillips* the Federal Circuit has emphasized the importance of the specification in claim construction. In doing so, the Court recognized that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice, but offered the following advice:

[T]he line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.

Id. at \*55.

And continued:

In the end, there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature. While that task may present difficulties in some cases, we nonetheless believe that

attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification.

*Id.* at \* 57.

With the foregoing instructions in mind, the Court will now proceed with the task of interpreting the disputed terms in the claims of the three patents that are the subject of this suit.

#### THE '353 PATENT

The '353 patent is entitled "Non-Invasive Multiprogrammable Stimulator and Method." The application for the patent was filed on May 7, 1986, and patent was issued on December 27, 1988. The abstract describes the patent as follows:

An electronic tissue stimulator system is provided comprising a plurality of electrodes to be implanted adjacent tissue to be stimulated in a patient. A transmitting means transmits stimulation pulses for stimulating the electrodes and programming data defining which of the electrodes are to be stimulated and the electrical polarity of the electrodes relative to one another. A receiver to be surgically-implanted within the patient which receives the stimulation pulses and the programming data, and delivers the energy in the stimulation pulses to the electrodes as defined by the programming data. Using an internal voltage source, only the programming data need be transmitted which define electrode selection and polarity and stimulation pulse parameters. Physical parameters can be measured and used to modify programming data. Dose periods are defined by programming data and/or a combination of programming data and physical parameter measurements.

The patent contains a total of 18 claims. Claims 1, 12, 16, and 17 are independent claims. Claims 1 through 8, 12

through 15, 17 and 18 are being asserted in this case and all of these claims are directed to the second embodiment set forth in the specification.

### DISPUTED CLAIM TERMS OF THE '353 PATENT AND THE COURT'S CONSTRUCTION OF THE TERMS

The disputed claim terms and the Court's construction of the meaning of the terms is set forth below

#### "programmably determining a positive, negative and high impedance state for each electrode" (appears in Claims 1, 12, 16)

The Court has concluded that this term should be construed as follows:

defining one of three polarity states-positive, negative, and high impedance-for each electrode according to data generated through programming activity.

## 2. "programming data" (appears in Claims 1-8, 10, 12, 14, 16-18)

The Court has concluded that this term should be construed as follows:

data comprising a sequence of coded instructions.

# 3. "to define for each of said electrodes said positive, negative or high impedance state" (appears in Claims 1, 16)

The Court has concluded that this term should be construed as follows:

to define a positive, negative, or high impedance state for each electrode.

# 4. "receiving means" (appears in Claims 1, 12, 16, 17)

The Court has concluded that this term should be construed as follows:

"Receiving means" is a structure that can be surgically implanted within the patient that includes a means for receiving the stimulation pulses and the programming data and means for delivering the energy of the stimulation pulses to the electrodes as defined in the programming data.

#### 5. "generating stimulation pulses" (appears in Claims 1, 7)

The Court has concluded that this term should be construed as follows:

producing pulses of electric current that can be delivered through electrodes to stimulate tissue.

# 6. "delivering said stimulation pulses to said electrodes having positive and negative states as defined by said programming data" (appears in Claims 1, 16)

The Court has concluded that this term should be construed as follows:

delivering the generated stimulation pulses to the electrodes that have positive and negative polarity states as defined by the programming data.

# 7. "define said stimulation pulses [or defining said stimulation pulses]" (appears in Claims 2, 7)

The Court has concluded that this term should be construed as follows:

define the amplitude, pulse width, and frequency of the stimulation pulses that are to be generated.

#### "programming data to define said stimulation pulses" (appears in Claim 2)

The Court has concluded that this term should be construed as follows:

data, generated through programming activity, to define the amplitude, pulse width, and frequency of the

stimulation pulses that are to be generated.

#### 9. "generating said stimulation pulses as defined by said programming data" (appears in Claim 2)

The Court has concluded that this term should be construed as follows:

producing the stimulation pulses according to the amplitude, pulse width, and frequency defined by the programming data.

# 10. "storing said programming data for more than one stimulation pulse"

(appears in Claim 3)

The Court has concluded that this term should be construed as follows:

recording said programming data in an electronic device such that the data can be obtained as needed to define a single electrode polarity configuration applied for more than one stimulation pulse and the programming data need not be re-transmitted each time a stimulation pulse is delivered.

# 11. "controlling the relative polarity of said stimulated electrodes during application of consecutive stimulation pulses to said electrodes without programming data in addition to the initial programming data" (appears in Claim 4)

The Court has concluded that this term should be construed as follows:

controlling whether pulses are delivered in a monophasic or biphasic mode based on programming data stored in the memory means such that the programming data need not be retransmitted each time a stimulation pulse is delivered.

### 12. "a monophase or biphase programming data" (appears in Claim 5)

The Court has concluded that this term should be construed as follows:

data, generated through programming activity, that specifies whether the stimulation pulses are to be monophasic or biphasic.

# 13. "defining a monophase or biphase programming data to be used to control said mono/biphasic control means" (appears in Claim 5)

The Court has concluded that this term should be construed as follows:

defining data, through programming activity, to control whether the stimulation pulses are to be monophasic or biphasic.

# 14. "generating programming data defining a pair of any two of said plurality of electrodes to be stimulated in a given relative polarity"

(appears in Claim 6)

The Court has concluded that this term should be construed as follows:

generating, through programming activity, data defining relative polarity states for any pair of the electrodes that are to be stimulated.

# 15. "applying said stimulation pulses to said two defined electrodes in said defined relative polarity" (appears in Claim 6)

The Court has concluded that this term should be construed as follows:

the electrical pulses are delivered to the pair of electrodes in the relative polarity defined by the programming data.

# 16. "generating programming data defining said stimulation pulses"

(appears in Claim 7)

The Court has concluded that this term should be construed as follows:

generating through programming activity, data defining

the stimulation pulses.

# 17. "generating stimulation pulses as defined by said programming data" (appears in Claim 7)

The Court has concluded that this term should be construed as follows:

producing the stimulation pulses as defined by the programming data.

18. "generating said programming data defining amplitude, frequency and pulse width of said stimulation pulses" (appears in Claim 8)

The Court has concluded that this term should be construed as follows:

generating the programming data to define the amplitude, frequency, and pulse width of the stimulation pulses.

19. "defining which of said electrodes are to be stimulated, the electrical polarity of said electrodes relative to one another" (appears in Claim 12)

The Court has concluded that this term should be construed as follows:

the programming data contains information that defines a positive or negative state for each electrode.

20. "generating a series of pulses during a dose period defined by said programming data" (appears in Claim 12)

The Court has concluded that this term should be construed as follows:

creating a plurality of electrical pulses, having a like relationship to each other, during a dose period, which dose period is defined by the programming data.

21. "delivering the energy of said stimulation pulses to said electrodes in said electrical polarity as defined by said programming data"

#### (appears in Claim 12)

The Court has concluded that this term should be construed as follows:

delivering the energy of the generated stimulation pulses to the electrodes in the relative polarity states defined by the programming data.

# 22. "responsive to said dosing period" (appears in Claim 13)

The Court has concluded that this term should be construed as follows:

acting in response to the programmed dose period.

# 23. "physiological parameter" (appears in Claim 14)

The Court has concluded that this term should be construed as follows:

a parameter characteristic of or appropriate to the healthy or normal functioning of the patient's body.

### 24. "sensing physiological parameters" (appears in Claim 14)

The Court has concluded that this term should be construed as follows:

measuring parameters characteristic of or appropriate to the healthy or normal functioning of the patient's body and converting those measurements into electrical signals.

### 25. "modifying said programming data as a function of said sensed parameters" (appears in Claim 14)

The Court has concluded that this term should be construed as follows:

altering the programming data, which is to be transmitted from the transmitting means to the receiving means, based on measurements of the parameters characteristic of or appropriate to the healthy or normal functioning of the patient's body.

26. "defining for each electrode a positive, negative and high impedance state" (appears in Claim 17)

The Court has concluded that this term should be construed as follows:

defining one of three polarity states -- positive, negative, and high impedance -- for each electrode.

27. "selecting programming data defining for each electrode a positive, negative and high impedance state" (appears in Claim 17)

The Court has concluded that this term should be construed as follows:

selecting data, which was generated through programming activity, defining one of three polarity states -- positive, negative, and high impedance -- for each electrode.

28. "to select which of said electrodes will be stimulated and the electrical polarity of said electrodes" (appears in Claim 17)

to select which of the electrodes will be stimulated and the polarity states of the electrodes.

29. "an individual set of programming data" (appears in Claims 10, 18)

The Court has concluded that this term should be construed as follows:

a collection or group of data which defines the state of each electrode as a positive, negative, or high-impedance output.

30. "selecting an individual set of programming data" (appears in Claim 18)

The Court has concluded that this term should be construed as follows:

selecting an individual set of data that has been generated through programming activity.

In construing the foregoing terms, the Court has relied on the intrinsic evidence and has in addition relied on "Webster's 3rd International Dictionary, 1981" for definition of the word "psysiological."

### DETERMINATION OF CORRESPONDING STRUCTURE FOR RECITED FUNCTIONS IN MEANS-PLUS-FUNCTION CLAIMS

A. "means connected to said electrodes for programmably determining a positive, negative and high impedance state for each electrode" (appears in Claim 1)

The Court finds the corresponding structure as follows:

microprocessor 500; RAM 503; ROM 505; associated software; data registers 42; and electrode polarity decoder 52.

B. "transmitting means for transmitting programming data to define for each of said electrodes said positive, negative or high impedance state" (appears in Claim 1)

The Court finds the corresponding structure as follows: external programmer 700.

C. "receiving means to be surgically implanted within said patient" (appears in Claim 1)

The Court finds the corresponding structure as follows: receiver 12.

D. "receiving means . . . for receiving said programming data"
(appears in Claim 1)

The Court finds the corresponding structure as follows:

transceiver 22.

E. "receiving means . . . for generating stimulation pulses" (appears in Claim 1)

current source 600 and electrode output switches 34.

F. "receiving means . . . for delivering said stimulation pulses to said electrodes having positive and negative states as defined by said programming data" (appears in Claim 1)

electrical connections in receiver 12 that connect electrode output switches 34 to lead wires 18.

G. "means for transmitting programming data to define said stimulation pulses" (appears in Claim 2)

external programmer 700.

H. "means for generating said stimulation pulses as defined by said programming data" (appears in Claim 2)

current source 600 and electrode output switches 34

I. "memory means for storing said programming data for more than one stimulation pulse" (appears in Claim 3)

data registers 42

J. "mono/biphasic control means connected to said memory means for controlling the relative polarity of said stimulated electrodes during application of consecutive stimulation pulses to said electrodes without programming data in addition to the initial programming data" (appears in Claim 4)

The Court finds the corresponding structure as follows:

microprocessor 500; RAM 503; ROM 505; and associated software.

K. "means for defining a monophase or biphase programming data to be used to control said mono/biphasic control means" (appears in Claim 5)

The Court finds the corresponding structure as follows:

external programmer 700.

L. "means for generating programming data defining a pair of any two of said plurality of electrodes to be stimulated in a given relative polarity" (appears in Claim 6)

The Court finds the corresponding structure as follows:

external programmer 700.

M. "means for applying said stimulation pulses to said two defined electrodes in said defined relative polarity" (appears in Claim 6)

The Court finds the corresponding structure as follows:

current source 600; electrode output switches 34; and electrical connections in receiver 12 that connect electrode output switches 34 to lead wires 18.

N. "means for generating programming data defining said stimulation pulses" (appears in Claim 7)

The Court finds the corresponding structure as follows:

external programmer 700.

O. "means for generating stimulation pulses as defined by said programming data" (appears in Claim 7)

The Court finds the corresponding structure as follows:

current source 600 and electrode output switches 34.

P. "means for generating said programming data defining amplitude, frequency and pulse width of said stimulation pulses" (appears in Claim 8)

The Court finds the corresponding structure as follows:

external programmer 700.

Q. "means connected to said electrodes for programmably determining a positive, negative and high impedance state for each electrode" (appears in Claim 12)

The Court finds the corresponding structure as follows:

microprocessor 500; RAM 503; ROM 505; associated software; data registers 42; and electrode polarity decoder 52.

R. "transmitting means for transmitting programming data defining which of said electrodes are to be stimulated, the electrical polarity of said electrodes relative to one another and a dose period" (appears in Claim 12)

The Court finds the corresponding structure as follows: external programmer 700.

S. "receiving means to be surgically implanted within said patient" (appears in Claim 12)

The Court finds the corresponding structure as follows:

Receiver 12.

T. "receiving means . . . for receiving said programming data" (appears in Claim 12)

The Court finds the corresponding structure as follows: transceiver 22.

U. "receiving means . . . for generating a series of pulses during a dose period defined by said programming data" (appears in Claim 12)

The Court finds the corresponding structure as follows: current source 600 and electrode output switches 34.

V. "receiving means . . . for delivering the energy of said stimulation pulses to said electrodes in said electrical polarity as defined by said programming data" (appears in Claim 12)

The Court finds the corresponding structure as follows:

electrical connections in receiver 12 that connect output switches 34 to lead wires 18.

W. "means responsive to said dosing period for defining periods of stimulation and non-stimulation" (appears in Claim 13)

The Court finds the corresponding structure as follows:

Master clock 520; counter 526; and on/off control 530.

### X. "means for sensing physiological parameters" (appears in Claim 14)

The Court finds the corresponding structure as follows:

sensor inputs 620; analog to digital converter 622; microprocessor 500; ROM 505; associated software; and external programmer 700.

# Y. "means for modifying said programming data as a function of said sensed parameters" (appears in Claim 14)

The Court finds the corresponding structure as follows: microprocessor 500; ROM 505; and associated software.

#### Z. "means for modifying said dose period" (appears in Claim 15)

The Court finds the corresponding structure as follows: external programmer 700.

#### AA. "implanting a receiving means" (appears in Claim 17)

The Court finds the corresponding structure as follows: receiver 12.

### BB. "an electrode state selecting means in a patient" (appears in Claim 17)

The Court finds the corresponding structure as follows:

microprocessor 500, RAM 503; ROM 505; associated software; date registers 42; and electrode polarity decoder 52.

#### THE '045 PATENT

The '045 patent is entitled "Inplantable Lead and Method of Manufacture. The application for the patent was filed on April 26, 1999, and the patent was issued on April 10, 2001. The

invention is described in the abstract as:

An implantable, substantially isodiametric, low resistance implantable lead having at least one electrode positioned in a stimulation/sensing portion of the lead. At least the stimulation/sensing portion is unitized through partially surrounding and supporting insulation and conductive element(s) of the stimulation/sensing portion with a fused matrix of material having mechanical properties consistent with a body of the lead.

The patent has 14 claims, three of which are independent. All claims are asserted.

The objects of the invention are set out in the background of the invention in Column 2 as follows:

An object of the present invention is to avoid the shortcomings of known leads and manufacturing techniques for the same.

Another object of the present invention is to provide a method of forming a lead having a true isodiametric body for at least the stimulation/sensing portion of the lead.

Another object of the present invention is to provide a lead having a true isodiametric body for at least the stimulation, sensing portion of the lead.

Another object of the present invention is to provide a lead having a low resistance from a terminal to a coupled electrode to reduce energy consumption during system operation.

Other aspects, objects, and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following Specification together with the provided drawings.

### DISPUTED CLAIM TERMS OF THE '045 PATENT AND THE COURT'S INTERPRETATION OF THE TERMS

The meaning of the following claim terms is disputed and the

Court has interpreted the claims as follows:

#### a. "prescribed" (appears in claims 1, 12, 14)

Plaintiff has requested that the meaning of this word be construed. The Court is of the opinion that no construction is necessary.

#### b. "mechanical properties" (appears in Claims 1, 9, 12, 14)

Plaintiff has requested that the meaning of this word be construed. The Court is of the opinion that no construction is necessary.

#### c. "lead body is formed of a material having prescribed mechanical properties" (appears in Claims 1, 12, 14)

lead body is formed of a material that is non-reactive to the environment of the human body and provides a flexible and durable "i.e. fatigue resistant" exterior structure for the lead and insulates adjacent terminals and/or electrodes.

#### d. "insulative" (appears in Claims 1-3, 8-12, 14)

The Court has concluded that this term should be construed as follows:

serving to electrically insulate.

#### e. "consistent with" (appears in Claims 1, 9, 12, 14)

The Court has concluded that this term should be construed as follows:

similar to and compatible with.

# f. "insulative material having mechanical properties consistent with the material of the lead body" (appears in Claims 1, 9, 12, 14)

The Court has concluded that this term should be construed as follows:

a material serving to electrically insulate that has physical characteristics similar to and compatible with the physical characteristics of the material of the lead body including the characteristics of non-

reactivity to the human body, flexibility, durability and strength.

#### g. "interior passage" (appears in Claims 1, 6, 9)

The Court has concluded that this term should be construed as follows:

space within an object through which another object may pass.

## h. "an [the] interior passage defined within [by] the lead body, first region, and second region" (appears in Claims 1 and 6)

The Court has concluded that this term should be construed as follows:

a space defined within the lead body, first region, and second region through which another object may pass.

#### i. "substantially" (appears in Claims 1, 6, 7, 9, 12)

The Court has concluded that this term should be construed as follows:

to a considerable extent.

#### j. "filled" (appears in Claims 1, 9)

The Court has concluded that this term should be construed as follows:

occupied throughout.

#### k. "substantially filled" (appears in Claims 1, 9)

The Court has concluded that this term should be construed as follows:

filled to a considerable extent; occupied throughout with few to no voids.

#### "stylet guide" (appears in Claim 6)

The Court has concluded that this term should be construed as follows:

an elongated space along the axis of a lead.

#### m. "inlet" (appears in Claim 6)

The Court has concluded that this term should be construed as follows:

an opening.

#### n. "inlet of the stylet guide" (appears in Claim 6)

The Court has concluded that this term should be construed as follows:

an opening to the elongated space along the axis of the lead.

#### o. "surrounds" (appears in Claim 6)

The Court has concluded that this term should be construed as follows:

encloses on all sides.

#### p. "substantially surrounds" (appears in Claim 6)

surrounds to a considerable degree.

#### q. "isodiametric" (appears in Claim 7)

The Court has concluded that this term should be construed as follows:

having equal diameters.

#### r. "substantially isodiametric" (appears in Claim 7)

The Court has concluded that this term should be construed as follows:

isodiametric to a considerable degree; having a diameter with little to no variation.

#### s. "fused matrix" (appears in Claims 8, 11, 13, 14)

The Court has concluded that this term should be construed as follows:

material resulting from the melting together of one or more compatible materials.

#### t. "solid" (Claims 12, 14)

The Court has concluded that this term should be construed as follows:

formed with no voids.

#### u. "substantially solid" (appears in Claims 12, 14)

The Court has concluded that this term should be construed as follows:

solid to a considerable extent; formed with few to no voids.

#### v. "consistent mechanical characteristics" (appears in Claim 14)

The Court has concluded that this term should be construed as follows:

similar and compatible physical characteristics.

# w. "fused matrix of materials having consistent mechanical characteristics" (appears in Claim 14)

The Court has concluded that this term should be construed as follows:

material resulting from the melting together of one or more materials having similar and compatible physical characteristics.

In construing the foregoing terms, the Court has relied on the intrinsic evidence and has in addition relied on "Webster's 3<sup>rd</sup> International Dictionary, 1981" for definitions of the words "substantially", "solid", and "consistent."

#### THE '678 PATENT

The '678 patent is entitled "Stimulation Lead Connector."

The application for the patent was filed on March 19, 1999, and patent was issued on November 28, 2000. The abstract describes the patent as follows:

A stimulation lead connection assembly capable of easily receiving and engaging a stimulation lead for purposes of transmitting selected electrical energy to electrodes of a received stimulation lead. The connection assembly retains a stimulation lead in a manner that permits a user to freely insert (and/or withdraw) a steering mechanism, for example, a stylet, into the stimulation lead that is electrically engaged by the connection assembly.

The patent contains a total of 9 claims, three of which are independent. All claims are asserted in this case.

### DISPUTED CLAIM TERMS OF THE '678 PATENT AND THE COURT'S INTERPRETATION OF THE TERMS

#### a. "adapted" (appears in Claims 1, 4, 5, 7)

The Court has concluded that this term should be construed as follows:

suited by design to a particular use, purpose or situation.

#### b. "access" (appears in Claims 1, 5, 9)

The Court has concluded that this term should be construed as follows:

a way of approaching, entering, exiting, or making use of.

#### c. "selective[ly]" (appears in Claims 1, 2, 5, 6,9)

The Court has concluded that this term should be construed as

follows:

characterized by choice.

d. "to enable selective insertion or withdrawal" (appears in Claims 1, 5, 9)

The Court has concluded that this term should be construed as follows:

to enable a choice to insert or withdraw.

e. "the housing is adapted to provide access to a steering mechanism inlet of an engaged stimulation lead to enable selective insertion or withdrawal of a steering mechanism through such steering mechanism inlet" (appears in claims 1, 5, 9)

The Court has concluded that this term should be construed as follows:

the housing is suitable to provide a way of approaching, entering, exiting, or making use of a stylet opening of a stimulation lead that has been electrically engaged in the connector to allow a choice to insert or withdraw a stylet from the stylet opening.

f. "operatively guide" (appears in Claim 1)

The Court has concluded that this term should be construed as follows:

effectively directing toward a desirable course.

g. "the housing is further adapted to opeartively guide a distal end of a steering mechanism into a steering mechanism inlet of an engaged stimulation lead" (appears in Claim 1)

The Court has concluded that this term should be construed as follows:

the housing is further suitable to operate to assist in directing the distal end of a stylet into the stylet opening of a stimulation lead that has been electrically engaged in the connector.

In construing the foregoing terms, the Court has relied on

the intrinsic evidence and has in addition relied on "Webster's 3rd International Dictionary, 1981" for definitions of the words "selective", "adapted" and "access."

#### CONCLUSION

The jury will be instructed in accordance with the Court's definition set forth above of the foregoing words and terms.

IT IS SO ORDERED.

SIGNED this 15th day of August, 2005.

PAUL BROWN

SENIOR UNITED STATES DISTRICT JUDGE

Brown